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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,920

02/07/2005

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MUKA12

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,920	<b>Applicant(s)</b> MUKAI ET AL.	
	<b>Examiner</b> Lora E. Barnhart	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 2, 6, 7, and 21 as recited in the 1/7/09 claim listing are currently pending and under examination. Applicant's election with traverse of the  $\alpha$ -glucosyl saccharide species "liquefied starch" in the reply filed on 4/24/07 is still in effect.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/09 has been entered.

#### ***Specification***

The amendment filed 7/8/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The amendments to the specification completely change the meaning of the experimental data in the working examples. According to the new amendment, the table originally found at page 24 has been re-numbered as "Table 3," meaning that it relates to Experiment 4 ("Glucosyl-transferring reaction to L-ascorbic acid from various glucosyl saccharides as glucosyl donors") as well as to Experiment 8 ("Formation of AA-2G by the combinational use of  $\alpha$ -isomaltosyl glucosaccharide-forming enzyme and CGTase"). This table (originally numbered "Table 5" and found at page 31 of the specification) does not appear to

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include any data regarding "various glucosyl saccharides." Experiments 4 and 8 regard divergent subject matter that would not yield the same data as each other. Applicant is required to clarify this issue or to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC §§ 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 7, and 21 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamamoto et al. (1992, U.S. Patent 5,137,723).

Yamamoto teaches mixing maltose and L-ascorbic acid (L-AA) into a single solution, then adding rat intestine  $\alpha$ -glucosidase (RIAGase) to the solution to yield 2-O- $\alpha$ -D-glucopyranosyl-L-ascorbic acid (AA-2G; Experiment 2; column 9, line 8, through column 12, line 44). Yamamoto teaches that AA-2G may also be made using a method in which L-AA is combined with cyclodextrin in a solution to which is added cyclomaltodextrin glucanotransferase (CGTase; Examples A-1 and A-2, column 13, line

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20, through column 14, line 34). Yamamoto teaches that the yield of AA-2G is enhanced by contacting the reaction product of Example A-2 with glucoamylase (Example A-3; column 14, lines 35-62). Yamamoto teaches recovering AA-2G by purification on gel permeation and cation exchange columns, drying AA-2G with a vacuum, and isolating >99% pure crystals of AA-2G (column 9, lines 28-43 and column 13, line 32, though column 14, line 62, for example). Yamamoto teaches conducting their method using any of several  $\alpha$ -glucosyl saccharides, including liquefied starch (column 3, line 62, through column 4, line 3).

The RIAGase and CGTase of Yamamoto are both " $\alpha$ -isomaltosyl glucosaccharide-forming enzymes" in accordance with claim 1 in that they combine L-AA with  $\alpha$ -glucosyl saccharides to yield AA-2G.

The selection of the  $\alpha$ -glucosyl saccharide to include in the reaction mixture of Yamamoto would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Yamamoto teaches that the species recited in claim 1 are functional equivalents. A holding of obviousness over the cited claims is therefore clearly required.

Claim 1 describes the  $\alpha$ -isomaltosyl glucosaccharide-forming enzyme used in the method as being "obtained from the genera *Arthrobacter* or *Bacillus*," which is a product-by-process limitation. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

As discussed above, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants'  $\alpha$ -isomaltosyl glucosaccharide-forming enzyme that is obtained from *Arthrobacter* or *Bacillus* differs, and if so to what extent, from the RIAGase discussed in Yamamoto. Yamamoto's

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RIAGase has  $\alpha$ -isomaltosyl glucosaccharide-forming enzyme activity (i.e., it yields AA-2G from L-AA in the presence of an  $\alpha$ -glucosyl saccharide). The cited art demonstrates a reasonable probability that the enzyme of Yamamoto is either identical or sufficiently similar to the claimed enzyme that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The mere fact that a characteristic of the enzyme of Yamamoto (e.g., the levels of AA-5G and AA-6G produced by its reaction with L-AA) was not disclosed by Yamamoto does not make methods employing that enzyme patentable. Applicant's enzyme possesses inherent characteristics which might not have been displayed in the tests used in Yamamoto; in other words, the fact that Yamamoto did not test the levels of AA-5G and AA-6G remaining in the reaction mixture does not indicate that the levels were higher than those claimed. Clear evidence that the method and enzyme of the cited prior art does not possess a critical characteristic that is possessed by the **claimed** method and enzyme (i.e., the levels of AA-5G and AA-6G **across the entire scope of the claims**) would advance prosecution and might permit allowance of claims to applicants' method of using the enzyme.

Applicant alleges that the RIAGase of Yamamoto does not have the enzymatic functions recited in claim 1, referring again to the Nishimoto declaration in support of patentability (reply, page 10). Applicant alleges that the PINEDEX product used in the Nishimoto declaration is "a typical liquefied starch" (reply, pages 11-12). The arguments and evidence have been fully considered, but they are not persuasive.

To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. The term “nexus” designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. See M.P.E.P. § 716.01(b). In this case, the evidence in the Nishimoto declaration does not share a nexus with the claimed invention.

Applicant's reply establishes through prior art references that PINEDEX is a commercially available composition containing maltodextrin. Based on this fact, applicant alleges, “there are no substantial differences between maltodextrin and 'liquefied starch'” (reply, page 11 paragraph 3; and page 12, paragraph 3). The examiner submits that applicant is interpreting the term “liquefied starch” too narrowly. The term “liquefy” merely requires that a material be in liquid form; therefore, “liquefied starch” encompasses all liquid compositions containing starch. Applicant may be confusing “liquefied starch” with the more precise term “hydrolyzed starch.” BeMiller et al. (1996, in *Food Chemistry*; reference U) discuss several different compositions that are reasonably within the definition of “liquefied starch” but are not addressed by the Nishimoto declaration. BeMiller teaches “stirred moist starch” (page 199, paragraph 1), which is “liquid” in that it can be stirred, and “a slurry of starch in water,” which is also liquid (page 200, last paragraph). BeMiller discusses “thin-boiling starches,” which may



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be added to water to yield a suspension that is reasonably "liquefied." BeMiller also teaches that "more extensive modification" of starch with acid (i.e., hydrolysis) produces dextrans, indicating that maltodextrin (the relevant component of PINEDEX) arises only after other intermediate liquid products form (page 199, paragraphs 2 and 3).

Furthermore, BeMiller teaches that continuing hydrolysis of starch past the maltodextrin stage yields mono- and oligosaccharides (page 199, last paragraph et seq.). In short, there are numerous species of "liquefied starch" that are physically and chemically distinct from maltodextrin; the basis for applicant's statement that there are no substantial differences between maltodextrin and liquefied starch is not clear. Again, the scope of the Nishimoto declaration is limited to maltodextrin and does not investigate any other liquid compositions of starch or liquefied starches.

The examiner notes that she has examined claim 1 thus far only as far as it pertains to the elected species; however, in the event that the elected species is found to be allowable, applicant must either cancel the nonelected species or agree to continued prosecution in which the nonelected species are fully examined for patentability. Applicant should review M.P.E.P. § 821.04 and consider its provisions in preparing a reply to this Office action. Applicant should also note that the data in Experiment 4 and Table 2 do not clearly address all of the species, as discussed in the 6/17/09 Office action (page 8).

***No claims are allowed. No claims are free of the art.***

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP

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714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/  
Primary Examiner, Art Unit 1651